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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,574	08/01/2002	Gerard Ribes	1721-49	1529

21559 7590 10/04/2006

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
ZHANG, NANCY L	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,574	RIBES ET AL.	
	Examiner	Art Unit	
	Nancy L. Zhang	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 13-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 13-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on June 26, 2006 has been received and entered.

In view of applicant's amendment, the rejection of claims 1-3, 5-10 and 12-23 made in the last Office Action under 35 USC § 112, lack scope of enablement is hereby withdrawn.

Claims 4 and 6-12 are cancelled.

Claims 1-3, 5 and 13-43 are presented for examination.

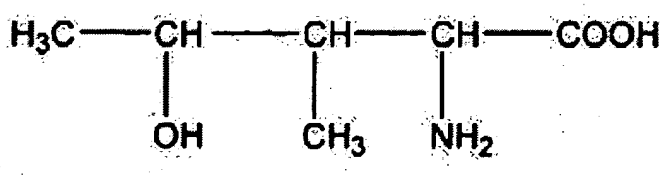
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

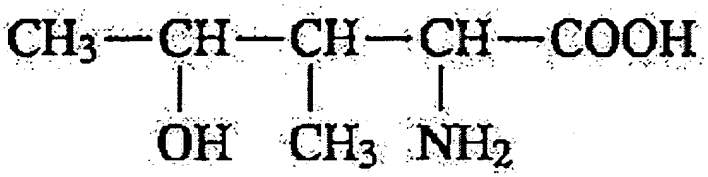
Claims 1-3, 5, 13, 15-16, 18 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sauvaire et al. (US Patent 5,470,879, issue date: Nov. 28, 1995).

Claims 1-3, 5, 13, 15-16, 18 and 23 recite a method of treating type II diabetes comprising administering 4-hydroxyisoleucine of formula



and/or the lactonic form thereof.

Sauvaire et al. disclose the treatment of Non-insulin dependent diabetes (type II diabetes) by the administration of 4-hydroxyisoleucine of the formula



or its lactone form or mixtures thereof (see column 7, lines 62-65).

Claim 18 limits that the 4-hydroxyisoleucine is administered orally. Sauvaire et al. disclose that the antidiabetic composition containing 4-hydroxyisoleucine may be administered orally (column 2, lines 48-50).

Therefore, the method of treating type II diabetes by administering 4-hydroxyisoleucine is clearly anticipated by Sauvaire et al.

Claim 15 recites that the 2S, 3R, 4S isomer of 4-hydroxyisoleucine is present in the formulation. It does not limit that the 2S, 3R, 4S isomer of 4-hydroxyisoleucine is the only effective form of 4-hydroxyisoleucine being administered in the method of treatment. Since the formula as claimed is identical to Sauvaire et al.'s formula, the recitation of claim 15 is viewed as merely a characteristic of the formula where an isomer form of 4-hydroxyisoleucine is present.

The "inducing an insulin sensitizing effect" or "insulin mimetic effect" in the preambles of claims 1, 15 and 26 is merely a property or function of the formula.

The recitation of claims 2 and 3 is merely a scientific explanation for the action mechanisms of 4-hydroxyisoleucine.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Therefore, claims 1-3, 5, 13, 15-16, 18 and 23 are clearly anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

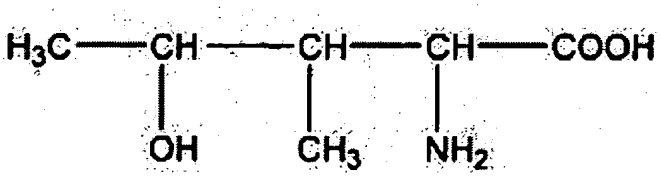
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-22 and 24-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauvaire et al. (US Patent 5,470,879, issue date: Nov. 28, 1995) in view of Guittard (US Patent 5,178,867, issue date: Jan. 12, 1993).

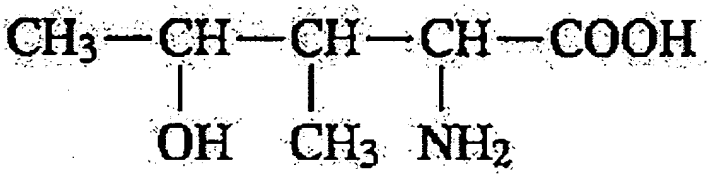
Claims 19-22 and 24-43 recite a method of treating type II diabetes comprising administering 4-hydroxyisoleucine of formula



and/or the lactonic form thereof where the administration is two or three times per day and the form of administration is a capsule or a tablet.

Claims 24-43 recite the limitation that the method comprises administering the (2S, 3R, 4S) isomer of 4-hydroxyisoleucine for the treatment of diabetes.

Sauvaire et al. disclose the treatment of Non-insulin dependent diabetes (type II diabetes) by the administration of 4-hydroxyisoleucine of the formula



or its lactone form or mixtures thereof (see column 7, lines 62-65).

Sauvaire et al. do not teach that 4-hydroxyisoleucine is administered twice or three times per day and the form of the 4-hydroxyisoleucine is a capsule or a tablet. However, Sauvaire et al. disclose that the composition of 4-hydroxyisoleucine contains excipients which are chosen in accordance with the pharmaceutical dosage form adopted (column 2, lines 51-53). Sauvaire et al. also disclose that the dosage can vary within wide limits and depend on each particular case to be treated (column 2, lines 54-56). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the dosage form of a capsule or a tablet and determine the number of administration of the drug per day for treating diabetes through routine experimentation using the teachings of Sauvaire et al. The motivation to do so is to make and use Sauvaire et al.'s invention for the treatment of diabetes and that the most convenient and economical form of drug administration is oral ingestion in dosage forms of tablets and capsules (Guittard, column 1, lines 19-24).

Sauvaire et al. do not teach the presence of the (2S, 3R, 4S) isomer of 4-hydroxyisoleucine in the active substance 4-hydroxyisoleucine being administered for treating diabetes. However, Sauvaire et al. disclose that the active substance can be of any origin, naturally or synthetically (column 2, lines 57-59). Therefore, it is reasonably

interpreted that the active substance administered by Sauvaire et al. comprises all random isomers of 4-hydroxyisoleucine including the (2S, 3R, 4S) isomer as what's claimed in claims 24-43.

Therefore, the invention as claimed in claims 19-22 and 24-43 was prima facie obvious over the combined teachings of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauvaire et al. (US Patent 5,470,879, issue date: Nov. 28, 1995) in view of Davydov (US Patent 4,529,589, issue date: Jul. 16, 1985).

Claim 14 recite a pharmaceutical composition or a kit for the treatment of type II diabetes comprising both insulin and 4-hydroxyisoleucine.

Claim 17 recite a method of treating type II diabetes comprising administering 4-hydroxyisoleucine with the further administration of insulin.

Sauvaire et al. teach an antidiabetic composition for the treatment of type II diabetes (column 1, lines 9-10) containing as active substance 4-hydroxyisoleucine (column 2, lines 32-45). Sauvaire et al. also disclose the treatment of Non-insulin dependent diabetes (type II diabetes) by the administration of 4-hydroxyisoleucine (column 7, lines 62-65). Sauvaire et al. do not teach insulin being administered for the treatment of diabetes. However, Davydov et al. teach that insulin is well known in the art as being used in medical practice for the treatment of diabetes mellitus (column 1, lines 14-16).

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior." Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine insulin and 4-hydroxyisoleucine in a pharmaceutical composition or to administer 4-hydroxyisoleucine with the further administration of insulin to a NIDDM patient, motivated by their having been taught by the prior art to be useful in treating diabetes, consonant with the reasoning of the cited case law.

Therefore, the invention as claimed in claims 14 and 17 was prima facie obvious over the combined teachings of the prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NLZ

Ardin H. Marschel 9/29/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER